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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 10/084,683 | 02/28/2002 | Anthony John Phillips | PHIL3004C/REF | 4369 |

7590 08/13/2003

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| EXAMINER |
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SHARAREH, SHAHNAM J

| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/084,683

Applicant(s)

PHILLIPS ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/28/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/107,847.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

1. Preliminary Amendments filed on July 12, 2002 and February 28, 2002 have been entered. Claims 10-26 are pending. Claims are free of art.

Specification

2. The title of the invention, "compositions," is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 10-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7 of U.S. Patent No. 6,020,001 (US '001) and claims 1-5 of U.S. Patent No. 5,863,559 (US '559). Although the conflicting claims are not identical, they are not patentably distinct from each other because at least one embodiment of the patented claims fall within the scope of the pending claims.

The patented claims of US '001 and US '559 are directed to pharmaceutical compositions comprising a film-coated tablet containing 3-[2-(dimethylaminoethyl)-N-methyl-1H-indole-5-methanesulfonamide succinate salt.

The difference between the patented claims and the instant pending claims are merely in scope. The instantly claimed composition is generic to the patented composition because the patented claims are directed to pharmaceutically acceptable succinate salts of the active ingredient instantly claimed. Therefore, the patented claims anticipate the limitations of the instant pending claims. Subsequently, it would have been obvious to one of ordinary skill in the art at the time to practice the pending claims when in possession of the patented compositions.

4. Claims 19-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,020,001 (US '001), claim 6 of U.S. Patent No. 5,863,559 (US '559), and claim 1 of U.S. Patent 6,368,627 (US '627). Although the conflicting claims are not identical, they are not patentably distinct from each other because at least one embodiment of the patented claims fall within the scope of the pending claims.

The patented claims of US '001 and US '559 are directed to methods of treating migraine comprising administering a film-coated tablet containing 3-[2-(dimethylamino)ethyl]-N-methyl-1H-indole-5-methanesulfonamide succinate salt. The difference between the patented claims and the instant pending claims are in that the instantly claimed methods employ compositions, which are generic to the compositions employed in the patented methods. Specifically, the patented claims employ

pharmaceutically acceptable succinate salts of the active ingredient instantly claimed. Therefore, the patented claims anticipate the limitations of the instant pending claims. Subsequently, it would have been obvious to one of ordinary skill in the art at the time to practice the instant pending claims when in possession of the patented claims.

The patented claim of US '627 is directed to methods of treating migraine comprising administering a film-coated tablet containing 3-[2-(dimethylaminoethyl)-N-methyl-1H-indole-5-methanesulfonamide salts or solvates thereof. The difference between the patented claims and the instant pending claims is in that the instantly claimed method employs compositions that further contain a pharmaceutically acceptable carrier or excipient. Further, the instant claims are directed to specific doses. Nevertheless, merely including a pharmaceutical acceptable carrier or excipient or optimizing the therapeutic dose would have been well within purview of an ordinary skill in the art, because such steps is conventional in the art of dosage formulations and the ordinary artisan would have had a reasonable expectation of success to improve the bioavailability and bioefficacy of such oral formulations. Therefore, it would have been obvious to one of ordinary skill in the art at the time to practice the instant pending claims once in possession of the patented claims.

Claim Objections

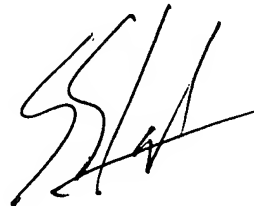
5. Claim 10-26 are objected to because of the following informalities: it appears that the active ingredient is misspelled. Diamethylaminoehyl portion of the active ingredient should read Diamethylaminoethyl. Appropriate correction is required.

Conclusion

6. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.



Shahnam Sharareh, PharmD
Patent Examiner
Art Unit 1617

ss
August 10, 2003